

### REMARKS-General

The amended independent claim 1 incorporates all structural limitations of the original claim 1 and includes further limitations previously brought forth in the disclosure. No new matter has been included. All claims 1-5 are submitted to be of sufficient clarity and detail to enable a person of average skill in the art to make and use the instant invention, so as to be pursuant to 35 USC 112.

#### Response to Rejection of Claims 1-5 under 35USC103

The Examiner rejected claims 1-5 over Miyahara et al (US 4,725,428) in view of Tanii et al (US 5,973,312) and Akita et al (Journal of Food Science, 1992, 57(3):629-634). Pursuant to 35 U.S.C. 103: "(a) A patent may not be obtained though the invention is **not identically** disclosed or described as set forth in **section 102 of this title**, if the **differences** between the subject matter sought to be patented and the prior art are such that the **subject matter as a whole would have been obvious** at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made."

In view of 35 U.S.C. 103(a), it is apparent that to be qualified as a prior art under 35USC103(a), the prior art must be cited under 35USC102(a)~(g) but the disclosure of the prior art and the invention are not identical and there are one or more differences between the subject matter sought to be patented and the prior art. In addition, such differences between the subject matter sought to be patented **as a whole** and the prior art are obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains.

In other words, the differences between the subject matter sought to be patent as a whole of the instant invention and Miyahara et al which is qualified as prior art of the instant invention under 35USC102 are obvious in view of Tanii et al and Akita et al at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains.

The applicant respectfully submits that in order to determine whether the differences between the subject matters sought to be patent as a whole of the instant invention and the primary prior art, Miyahara et al, are obvious in view of the

supplemental cited arts, Tanii et al and Akita et al, we have to identify all the differences between the claims of the instant inventions and Miyahara et al. The applicant respectfully identifies the differences between the claims of the instant invention and Miyahara et al as follows:

(a) In claim 1, "effective components composed with IgY and antiseptic" is claimed as a combination against dental caries bacteria, wherein Miyahara et al merely teaches a dental composition comprising an effective amount to inhibit the colonization of Streptococcus mutans and an effective amount to stabilize the antibody of a nonionic surface active agent without any mention of any IgY to dental caries bacteria.

(b) In claim 1, "IgY is prepared from streptococcus mutans type c and type d" is claimed, wherein Miyahara et al merely teaches the antibody against a strain or mutant of human streptococcus mutans serotype c, d, e, f, or g.

(c) In claim 1, "the antiseptic composed with at least one of potassium sorbate and sodium benzoate" is claimed, wherein Miyahara et al does not mention any potassium sorbate and sodium benzoate as the antiseptic. Accordingly, Miyahara et al merely teaches, in column 5, lines 11-13, the nonionic surface active agent prevents an antibody incorporated in the dental caries-preventive composition from being deactivated. Miyahara et al never mention the nonionic surface active agent includes any potassium sorbate and sodium benzoate. Therefore, the antiseptic of the instant invention is not equivalent to the nonionic surface active agent taught by Miyahara et al.

(d) In claims 1-5, the IgY is claimed to dental caries bacteria as the main objective to reduce cost of production and elevates titer of antibody. The main objective of Miyahara et al is to keep the antibody stable for a long period of time and hence permit the antibody to exhibit its effect with certainty over a long period of time. Throughout the entire description and claims of Miyahara et al, Miyahara et al specifically teaches the nonionic surface active agent selected from the group consisting of alkanolamide fatty acid esters having 9 to 18 carbon atoms in the fatty acid group and 2 to 3 carbon atoms in the alkanol group, sucrose fatty acid esters having 8 to 18 carbon atoms in the fatty acid group and a degree of esterification of 0.8 to 3, polyoxyethylene sorbitan fatty acid esters having 8 to 20 carbon atoms in the fatty acid group, 6 to 60 mol of ethylene oxide added and a degree of esterification of 1 to 3, polyoxyethylene fatty acid esters having 8 to 20 carbon atoms in the fatty acid group 1

to 60 mol of ethylene oxide added and mixtures thereof. It is apparent that **the nonionic surface active agent** is the main objective and achievement of Miyahara et al since Miyahara et al specifically emphasizes the incorporation of antibody with the nonionic surface active agent in the dental composition, while Miyahara et al did not provide any of such suggestion or description in its disclosure of incorporating IgY with at least one of potassium sorbate and sodium benzoate.

(e) "An additive amount of the IgY is at least 0.05% and additive amount of the potassium sorbate and the sodium benzoate is 0.005-0.02% respectively" as claimed in claim 2 in addition to what is claimed in claim 1 as a whole, wherein Miyahara et al merely teaches, in column 4, lines 19-20, the antibody is in an amount of 0.002 to 10% by weight and, in column 5, lines 7-9, the nonionic surface active agent may be 0.1 to 3% by weight. In other words, Miyahara et al did not provide any of such suggestion or description the ratio between IgY and antiseptic.

(f) "The additive amount of the IgY is preferably 0.05-0.2%" as claimed in claim 3 in addition to what is claimed in claim 1 as a whole, wherein Miyahara et al merely teaches, in column 4, lines 21, the antibody is preferably in amount of 0.005 to 5% by weight.

(g) "The combination is a liquid product used for oral cavity is packaged in pocket atomizer for spraying usage" as claimed in claim 4 in addition to what is claimed in claim 1 as a whole, wherein Miyahara et al merely teaches the dental caries-preventive composition of this invention may be packaged in a proper container for storage and convenient use without any specifically mention of any pocket atomizer containing the liquid product of the combination.

(h) "The combination which is a liquid food is packaged in sucking bottle" as claimed in claim 5 in addition to what is claimed in claim 1 as a whole, wherein Miyahara et al merely teaches the dental caries-preventive composition of this invention may be packaged in a proper container for storage and convenient use without any specifically mention of any sucking bottle containing the liquid food of the combination.

Whether the claims 1 to 5 as amended of the instant invention are obvious depends on whether the above differences (a) to (h) between the instant invention and

Miyahara et al are obvious in view of Tanii et al and Akita et al at the time of the invention was made.

Furthermore, the applicant respectfully submits that when applying 35 USC 103, the following tenets of patent law must be adhered to:

- (a) The claimed invention must be considered as a whole;
- (b) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
- (c) The references must be viewed without the benefit of hindsight vision afforded by the claimed invention; and
- (d) Reasonable expectation of success is the standard with which obviousness is determined.

Also, "The mere fact that a reference could be modified to produce the patented invention would not make the modification obvious unless it is suggested by the prior art." *Libbey-Owens-Ford v. BOC Group*, 4 USPQ 2d 1097, 1103 (DCNJ 1987).

Tanii et al merely teaches a liquid oral composition which comprises a cationic bactericide and hydroxypropylmethy cellulose packed into a container capable of ejecting or spraying in a predetermined amount without any suggestion of how such cationic bactericide be possibly added into the IgY to form the combination against dental caries bacteria of the instant invention. In addition, Tanii et al merely teaches, in column 5, lines 13-14, examples of the preservatives include sodium benzoate, potassium sorbate, and p-hydroxybenzoate esters. However, such preservatives are embodied to use with hydroxypropylmethy cellulose but not IgY. Furthermore, Tanii et al merely teaches hydroxypropylmethyl cellulose is contained in an amount of 0.5% to 5% by weight, the cationic bactericide is contained in an amount of 0.001% to 5.0% by weight, and in combination of preservatives in an amount of from 0.01 to 1.0% by weight which fails to suggest an additive amount of the IgY is at least 0.05% and additive amount of the potassium sorbate and the sodium benzoate is 0.005-0.02% respectively.

Tanii et al merely teaches the oral composition is packed into a container such as pump dispenser type or squeeze type. However, Tanii never mentions the

combination of IgY and antiseptic in liquid form packed in a pocket atomizer for spray usage or in sucking bottle.

Akita et al, on the other hand, merely teaches, in the introduction, "oral administration of immunoglobulins from chicken egg has been used successfully by Bartz et al (1980)" and "egg yolk is recognized as a very good source of specific antibody". Similarly, neither Miyahara et al nor Akita et al suggests a combination containing the above distinctive features (a) to (h) as claimed in the instant invention as well as any combination or possibility of providing IgY with at least one of potassium sorbate and sodium benzoate to form a combination against dental caries bacteria.

"To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited art references for combination in the manner claimed... [T]he suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness..." *In re Gorman*, 933 F.2d 982, 986, 18 USPQ 2d 1885, 1888 (Fed. Cir. 1991).

Accordingly, the applicant believes that neither Miyahara et al, Tanii et al nor Akita et al, separately or in combination, suggest or make any mention whatsoever of the difference subject features (a) to (h) as claimed in the amended claims 1 to 5 of the instant invention. Applicant believes that for all of the foregoing reasons, all of the claims are in condition for allowance and such action is respectfully requested.

### **The Cited but Non-Applied References**

The cited but not relied upon references have been studied and are greatly appreciated, but are deemed to be less relevant than the relied upon references.

In view of the above, it is submitted that the claims are in condition for allowance. Reconsideration and withdrawal of the objection are requested. Allowance of claims 1-5 at an early date is solicited.

Should the Examiner believe that anything further is needed in order to place the application in condition for allowance, he is requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,



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#### CERTIFICATE OF MAILING

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